

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: METOPROLOL SUCCINATE END-PAYOR
ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:
ALL ACTIONS

C.A. No. 06-71 (GMS)

**DEFENDANTS' PARTIAL MOTION TO DISMISS
PLAINTIFFS' FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT**

INTRODUCTION

Defendants hereby move pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) to dismiss all claims for relief in Plaintiffs' First Amended Consolidated Class Action Complaint (the "Amended Complaint") relating to or predicated upon inequitable conduct or *Walker Process* fraud.

In 2009, the Federal Circuit Court of Appeals held in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009) that a *minimally* sufficient pleading purporting to allege inequitable conduct must "identify the specific who, what, when, where, and how of the material misrepresentation or omission" and although knowledge and intent may "be averred generally," such knowledge and intent must be supported by sufficient alleged facts from which a court can reasonably infer that a specific accused individual "knew of the withheld material information or of the falsity of the material misrepresentation," and nevertheless "withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1327-29.

Fact discovery in this matter closed on September 30, 2011 and expert discovery is nearly complete. On March 16, 2012, the Court granted Plaintiffs leave to file their Amended Complaint, which Plaintiffs docketed on March 19, 2012 (DI 276). Plaintiffs have had ample

opportunity – and indeed enjoy the benefit of a fully developed evidentiary record – to ensure that their Amended Complaint met all standards for sufficiency.

Yet, Plaintiffs’ Amended Complaint fails to meet *Exergen*’s minimum standards on several fronts, any one of which is fatal to Plaintiffs’ claims premised on or relating to inequitable conduct or *Walker Process* fraud. Moreover, Plaintiffs fail to even allege the necessary “but for” materiality required to maintain both inequitable conduct and *Walker Process* fraud claims, much less facts to support such an inference. Therefore, assuming *arguendo* that Plaintiffs’ bare bones allegations could even survive *Exergen* scrutiny – which they cannot – Plaintiffs nonetheless fail to state cognizable claims.

Accordingly, Defendants bring this straightforward motion to dismiss Plaintiffs’ insufficiently pled and unviable claims, and respectfully request that the Court dismiss such claims with prejudice.

PLAINTIFFS’ AMENDED COMPLAINT

1. The Amended Complaint purports to allege inequitable conduct and *Walker Process* fraud via 21 short paragraphs. *See* Amended Complaint ¶¶ 82-104.

2. In sum, Plaintiffs allege that “Defendants failed to disclose to the PTO any facts relating to their action against Lejus in the Swedish Patent Office in October 1985, the assignment agreement reached between Astra and Lejus, or that Nitenberg had made metoprolol succinate at Astra in 1971.” Amended Complaint ¶ 99.

3. As to the impact of these purported falsities or omissions, in a conclusory fashion, Plaintiffs allege without any supporting facts or rationale, that the named inventors – Appelgren and Eskilson – were improperly named as inventors (*id.* ¶ 100), that the issue of inventorship is “highly material” (*id.* ¶ 101), that the non-disclosure of the mere dispute about inventorship

“was both material...and done with an intent to deceive to the patent examiner” (*id.* ¶ 102), that disclosure of the inventorship issue “would have undoubtedly affected a reasonable patent examiner’s decision to issue a patent” (*id.* ¶ 103), and therefore, the “‘161 and ‘154 patents were and are unenforceable *ab initio*” (*id.* ¶ 104).

ARGUMENT

I. Inequitable Conduct and Walker Process Fraud Both Require “But For” Materiality, and Must Be Pled With Particularity.

4. Plaintiffs must start from scratch and bear the heavy burden of both sufficiently pleading and proving inequitable conduct and *Walker Process* fraud.¹

5. Inequitable conduct and *Walker Process* fraud both indisputably require a showing of “but for” materiality *and* independent evidence of intent to deceive the PTO. *See Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F. 3d 1276, 1291 (Fed. Cir. 2011) (requiring “but for” materiality for inequitable conduct claims); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F. 3d 1059, 1070-71 (Fed. Cir. 1998) (requiring “but for” materiality for *Walker Process* fraud claims).

6. To properly state a claim for inequitable conduct during patent prosecution, one must allege that the patent applicant knowingly misrepresented or withheld material facts with a specific intent to deceive the PTO. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d at 1327 (Fed. Cir. 2009); *Kingsdown Medical Consultants Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

¹ At the time Plaintiffs filed their original Consolidated Class Action Complaint, the ‘161 and ‘154 patents had been deemed unenforceable by the Eastern District of Missouri. *In re Metoprolol Succinate Patent Litig.*, 2006 WL 120343, at *14-26 (E.D. Mo. Jan. 17, 2006). The Federal Circuit vacated that decision in 2007. *In re Metoprolol Succinate Patent Litig.*, 494 F.3d 1011, at 1020-21 (Fed. Cir. 2007). Thus, in filing this Amended Complaint, Plaintiffs have no basis for alleging or relying upon any prior finding of inequitable conduct.

7. Inequitable conduct and *Walker Process* fraud must be pled with particularity. In

Exergen, the Federal Circuit unequivocally set out the pleading standard:

In sum, to plead the "circumstances" of inequitable conduct with the requisite "particularity" under Rule 9(b), the pleading must identify the specific **who, what, when, where, and how** of the material misrepresentation or omission committed before the PTO. Moreover, although "knowledge" and "intent" may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of **underlying facts** from which a court may reasonably infer that a **specific individual** (1) **knew of the withheld material information or of the falsity of the material misrepresentation**, and (2) **withheld or misrepresented this information with a specific intent to deceive the PTO**.

Exergen, 575 F.3d at 1328-29 (emphasis added).

8. The Federal Circuit also stated that “[a]lthough ‘knowledge’ and ‘intent’ may be averred generally, our precedent, like that of several regional circuits, requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.” *Id.* at 1327 (citations omitted). The “inference of deceptive intent must be reasonable and drawn from a pleading's allegations of underlying fact to satisfy Rule 9(b), [and] this inference must be ‘the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.’” *Id.* at 1329 n. 5 (citations omitted).

9. Likewise, *Walker Process* fraud must be alleged with the same particularity. *See Transweb, LLC v. 3M Innovative Properties Co.*, 2011 WL 2181189, at *12 (D. N.J. June 1, 2011) (“*Walker Process* fraud must be pled with particularity under Fed. R. Civ. P. 9(b).”) (citation omitted); Fed. R. Civ. P. 9(b) (“[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.”).

II. It is Beyond Dispute that Plaintiffs’ Amended Complaint Fails to Plead Inequitable Conduct and *Walker Process* Fraud with the Required Particularity.

10. Citing inventorship concerns and disputes, Plaintiffs allege only *one* theory of inequitable conduct, and the *Walker Process* allegations rely *solely* on the same woefully deficient pleading. Thus, if Plaintiffs fail to plead inequitable conduct, they necessarily fail to state a *Walker Process* claim.

11. The Amended Complaint fails to sufficiently plead the requisite “who, what, when, where and how” of alleged inequitable conduct as follows:

a. No identification of “Who.” Only individuals that have a duty of disclosure can commit inequitable conduct. *See* 37 *CFR* 1.56 (“Each individual associated with the filing and prosecution of a patent application [has a duty of disclosure]”) (emphasis added). Plaintiffs do not identify any such specific duty bound individual(s) who allegedly, personally committed the alleged inequitable conduct. Rather, Plaintiffs’ allegations focus entirely on the acts of “Astra” or “Defendants” (*see* Amended Complaint ¶¶ 82-104). Failing to specifically name the duty bound individual(s) who committed the deceitful acts or omissions during prosecution dooms the allegation as a matter of law. *See Exergen*, 575 F.3d at 1328-29 (requiring the identification of a “specific individual”). Of the persons identified by name, not one of them is alleged to have even participated in the prosecution of the patents, much less committed acts that would rise to the level of inequitable conduct. *See generally* Amended Complaint ¶¶ 82-104.

b. No identification or explanation of “What” or “Where.” Plaintiffs rely solely on purported, non-specific, omissions. They allege that “Defendants failed to disclose any facts relating to their action against Lejus...the assignment agreement...or that Nitenberg had made metoprolol succinate[,]” (Amended Complaint ¶ 104) (emphasis added), but stop well

short of identifying the specific omitted material facts that should have been disclosed but were withheld or that the failure to disclose was coupled with a specific intent to deceive. Plaintiffs further fail to allege that a specific duty-bound individual understood and appreciated the materiality of the omitted information but nevertheless withheld it with a specific intent to deceive, as required.² Just as it is insufficient to plead only that an applicant failed to disclose a prior art patent without identifying the specific claims and limitations, *Exergen*, 575 F.3d at 1329, Plaintiffs must do more than simply provide a laundry list of possible topics that should have been disclosed. Moreover, Plaintiffs allege that Defendants named the incorrect inventors (Amended Complaint ¶ 100), but do so without any factual basis to support that contention (*e.g.* upon what facts do Plaintiffs base their contention that inventorship is incorrect, and who is/are the correct inventor(s))? This is the antithesis of pleading with particularity.

c. Plaintiffs' Amended Complaint does not identify "How." Plaintiffs allege that the issue of inventorship is *per se* material (Amended Complaint ¶¶ 101-103), but the Amended Complaint contains no facts or allegations that would "explain both 'why' the withheld information is material...and 'how' an examiner would have used this information in assessing the patentability[.]" *Exergen*, 575 F.3d at 1329-1330. Plaintiffs state that facts relating to disagreements about inventorship should have been disclosed. But nowhere does the Amended Complaint allege that a specific duty bound person misled the PTO about the inventorship with deceptive intent.³

² Plaintiffs cite to the MPEP in support of their allegation of materiality (Amended Complaint ¶ 102), but nowhere do Plaintiffs identify any specific, accused duty bound person who allegedly knew about purported material information, fully appreciated its significance, and nevertheless withheld information about the inventorship dispute with the requisite intent to deceive.

³ Merely being incorrect is not enough; the allegedly erroneous designation of inventorship must be alleged with particularity as to why it is incorrect and that it arose by deceptive act or omission by a duty bound person—facts missing entirely from Plaintiffs' Amended Complaint.

d. Plaintiffs' Amended Complaint does not identify "When." Given the pleading deficiencies identified above, it comes as no surprise that Plaintiffs fail to identify "when" – when did the unnamed duty bound actors learn of the allegedly material information, when should they have disclosed it, and when did they decide to withhold it?

12. The failure to plead the foregoing elements with the required particularity is fatal to Plaintiffs' claims of inequitable conduct and *Walker Process* fraud. Moreover, the failure to provide a sufficient factual basis for their claims precludes an inference of intent to deceive. Plaintiffs fail to plead facts that "give rise to a reasonable inference of scienter, including both (1) knowledge of the withheld material information or of the falsity of the material misrepresentation, and (2) specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1330. A pleader must provide facts reasonably inferring "that, at the time of the allegedly false statement, the individual who made this statement to the PTO was aware of an allegedly contradictory statement." *Id.* (emphasis added). Here, Plaintiffs do not even identify the "who," thus rendering it impossible for them to plead sufficient allegations of knowledge of the withheld information or a specific intent to deceive.

13. Plaintiffs have failed to plead inequitable conduct and *Walker Process* fraud with particularity as required by *Exergen* and Federal Rule of Civil Procedure 9(b). Accordingly, Defendants respectfully request that Plaintiffs' claims premised on *Walker Process* fraud or inequitable conduct (*i.e.*, Plaintiffs' improper Orange Book listing and sham litigation claims premised on inequitable conduct) be dismissed with prejudice.

III. Even if *Exergen* and Rule 9(b) did not Require Minimally Sufficient Allegations, the Amended Complaint Fails to State a Viable Claim Because it Fails to Allege “But For” Materiality.

14. As noted above, both inequitable conduct and *Walker Process* fraud require “but for” materiality. Plaintiffs’ Amended Complaint does not allege “but for” materiality. *See generally* Amended Complaint ¶¶ 82-104.

15. Instead, it alleges that inventorship is “highly material,” “a reasonable examiner would consider it important,” and that disclosure would have “undoubtedly affected a reasonable patent examiner’s decision to issue a patent.” *Id.* ¶¶ 101-103. Thus, at best, Plaintiffs’ Amended Complaint pleads conclusory allegations of a lesser, inapplicable standard of materiality. In any event, putting aside conclusory allegations, it is the absence of facts from which “but for” materiality can be inferred that is fatal to Plaintiffs’ claims of inequitable conduct and *Walker Process* fraud. Defendants respectfully suggest that in order to state a viable claim of “but for” materiality, Plaintiffs must allege (with particularity) that the named inventors are not the correct inventors, and that the ‘161 and ‘154 patents would not have issued “but for” the designation of the incorrect inventors.

16. In the absence of factual allegations to support an inference of “but for” materiality, Plaintiffs have simply failed to state a claim upon which relief may be granted. *See, e.g., Human Genome Sciences, Inc. v. Genentech, Inc.*, 2011 WL 7461786, at *7 (C.D. Cal. Dec. 9, 2011) (dismissing claim for inequitable conduct in the absence of facts which would support an inference of “but for” materiality); *Hansen Manufacturing Corp. v. Enduro Sys., Inc.*, 2011 WL 5526627, at *4-5 (D. S.D. Nov. 14, 2011) (denying motion to amend to assert inequitable conduct on the basis of futility where “but for” materiality was not sufficiently pled); *Human Genome Sciences, Inc. v. Genentech, Inc.*, 2004 WL 5327194, at *3-4 (C.D. Cal. Feb. 18, 2004)

(denying leave to amend to assert a *Walker Process* fraud claim where allegations lacked sufficient facts to support “but for” materiality).

17. Accordingly, Plaintiffs’ Amended Complaint is not only deficient because it fails to allege “but for” materiality, but also because it fails to allege sufficient facts to support an inference of “but for” materiality. For these reasons, Defendants respectfully request that Plaintiffs’ claims premised on *Walker Process* fraud or inequitable conduct (*i.e.*, Plaintiffs’ improper Orange Book listing and sham litigation claims premised on inequitable conduct) be dismissed with prejudice pursuant to Rule 12(b)(6).⁴

CONCLUSION

In light of the foregoing points and authorities, Defendants respectfully request that Plaintiffs’ Amended Complaint be dismissed with prejudice with regard to any allegations, claims and/or counts relating to *Walker Process* fraud or inequitable conduct.

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⁴ Dismissal with prejudice is particularly appropriate where Plaintiffs’ own expert has already testified that Toivo Nitenberg is not an inventor under U.S. law, and his testimony fails to establish “but for” materiality. *See* DI 273-1 (excerpts from the deposition of John T. Goolkasian). Therefore, any proposed further amendment would be futile.